AUG 1 0 2000

TRADITIONAL 510(k)

510(k) Summary

510(k) Number: K002063

Date Prepared: July 5, 2000

Applicant Information:

Applicant: Bryan Corporation
4 Plympton Street
Woburn, MA 01801

Contact: Rose Logsdon
Marketing Director

Phone: (781) 935-0004, ext. 15
Fax: (781) 935-7602

Device Information:

Trade Name: BIOTRACE® Bone Cement Radio-Opacifier

Common Name: Barium Sulfate USP

Equivalent Devices:
The subject device is substantially equivalent to Parallax Tracer Radiopaque Particles (K991893).

Intended Use:
Biotrace Bone Cement Radio-Opacifier is intended for use as an additive to Codman Cranioplastic (Type 1 – Slow Set) to provide radiopacity for imaging purposes.

Comparison to Predicate Devices:
This device has the same functional characteristics as the predicate device.

Non-clinical Test Results:
Performance testing demonstrated that the end product (Cranioplastic and Tracer Particles) is substantially equivalent to Cranioplastic alone, with regards to functional characteristics.

Summary:
Based on the product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Ms. Rose S. Logsdon
Marketing Director
Bryan Corporation
Four Plympton Street
Woburn, Massachusetts 01801

Re: K002063
Trade Name: Biotrace Model 1730
Regulatory Class: II
Product Code: MYU
Dated: June 29, 2000
Received: July 7, 2000

Dear Ms. Logsdon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Barbara Zimmerman for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K002063

Device Name: Biotrace® Bone Cement Radio-Opacifier

Indications for Use:

Biotrace Bone Cement Radio-Opacifier is intended for use as an additive to Codman Cranioplastic (Type 1 – Slow Set) to provide radiopacity for imaging purposes.

(Please Do Not Write Below This Line – Continue on Another Page if Needed.)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over the Counter Use____ (Optional Format 1-2-96)

Barbara Bennison for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002063